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Original Research

Long-term follow-up of patients with Contained Annulus Ruptures after TAVI: the EuropeaN COntained RupturE ENCORE-registry

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Short title: **Follow-up of contained annulus ruptures post-TAVI**

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Abstract

Aims: The purpose of this registry was to determine the long-term outcomes in patients with asymptomatic contained annulus rupture (CR) as a rare complication of transcatheter aortic valve implantation (TAVI).

Methods and results: The ENCORE-registry is a multicenter registry (6 centers across Europe) of patients with CR diagnosed on post-TAVI computed tomography angiography (CTA) or transoesophageal echocardiography (TEE).

A total of 21 patients (mean age 81.9±4.1 years, 81% balloon-expandable TAVI-prostheses) were diagnosed with CR (mean size of lesions was 15.3±6.9 x 8.5±3.3 x 8.5±2.3 mm). Seventeen were diagnosed among a total of 1602 consecutive routine post-TAVI CTA (incidence 1.1%), two in TEE and two in post-TAVI CTA (each conducted due to suspicion of peri-interventional complications). During a mean follow-up of 2.3±1.7 years (cumulative 48.6 patient years) nine patients (43%) died from non-cardiac causes. None of the patients exhibited symptoms or underwent interventional treatment related to the CR, no sudden cardiac death occurred. A follow-up CTA, performed in eleven patients 240±176 days post-TAVI, revealed stable CR findings in seven, regression in one, and remission in three patients.

Conclusions: The results of our international multicenter registry demonstrate favourable long-term outcomes of CR after TAVI supporting a watch-and-wait strategy in these patients.

Key words: Annulus rupture; Aortic stenosis; Degenerative valve; Non-invasive imaging; Risk stratification; TAVI

Condensed Abstract

The international multicenter ENCORE-registry evaluated the long-term outcomes of 21 patients with asymptomatic contained annulus ruptures (CR, incidence 1.1%) after transcatheter aortic valve implantation (TAVI). During a mean follow-up of 2.3±1.7 years none of the patients exhibited symptoms or underwent interventional treatment related to the CR, no sudden cardiac death occurred. A follow-up computed tomography angiography, performed in eleven patients 240±176 days post-TAVI, revealed stable CR findings in seven, regression in one, and remission in three patients. Therefore, our results demonstrate favourable long-term outcomes of patients with CR after TAVI supporting a watch-and-wait strategy in these patients.

Abbreviations

CR = contained ruptures of the aortic annulus

CTA = computed tomography angiography

DAPT = dual antiplatelet therapy

ECG = electrocardiogram

SD = standard deviation

TAVI = transcatheter aortic valve implantation

TEE = transoesophageal echocardiography

THV = transcatheter heart valve

Introduction

One of the most threatening complications to TAVI is the rupture of the aortic root or annulus with an estimated incidence of 0.9%[1,2]. Besides immediately clinically apparent ruptures, asymptomatic contained ruptures of the aortic annulus (CR) have been diagnosed as an incidental finding on computed tomography angiography (CTA) performed after TAVI with an incidence up to 5%[3]. Risk factors for the occurrence of CR are severe transcatheter heart valve (THV) oversizing and increased calcification of the device landing zone[2,3].

However, information of outcomes in the event of CR is scared and limited to the direct post-interventional period or as longer-term follow-up in case reports[2,4-7]. Recently, we published an international case collection with long-term observation for a follow-up period of 2.5±1.5 years, in which all patients remained asymptomatic without specific treatment[8]. These results supported a wait-and-watch strategy in patients with CR. However, our data were limited through a restricted sample size (twelve patients from three TAVI-centers) and the fact that all patients were treated with balloon-expandable THVs.

Therefore, the purpose of this study was to determine the long-term outcomes in patients with CR from a larger international, multicenter registry.

Methods

Registry design

The ENCORE Registry (EuropeaN COntained RupturE Registry) was designed to collect data from centers across Europe having cases with CR. The registry was not supported by any external funding. This retrospective analysis included patients with TAVI performed before October 2017. A total of 6 centers across Europe (three in Germany, two in Denmark and one in the United Kingdom) contributed all their CR cases to the registry. The 12 patients with a CR from our previously published international case collection were re-enrolled in the ENCORE registry with a renewed follow-up[8].

A CR, diagnosed on post-TAVI CTA or transoesophageal echocardiography (TEE), was defined as a peri-annular pseudo-aneurysm formation with connection to the intra-aortic lumen, in contrast to an intramural haematoma with the integrity of all vascular wall layers (Figure 1). Pseudo-anonymized data collection was performed via dedicated case report forms including baseline, peri-interventional, and clinical follow-up data at pre-specified time points (1 to 5 years). In cases of death or development of cardiovascular symptoms the information was evaluated for a possible connection to the CR by two independent cardiologists.

TAVI procedure

In all patients the eligibility for TAVI, the preferred access route and the valve size selection were determined by institutional multidisciplinary heart teams, based on either pre-procedural TEE- or CTA-imaging. The procedure was performed via a transapical or transfemoral access using standard techniques[9]. THV-Implantations were mainly performed under general anaesthesia using fluoroscopy guidance. At the time of the intervention all patients gave their written informed consent for the anonymized use of clinical, procedural, and follow-up data.

CTA-Image acquisition

The pre- and post-TAVI CTAs were performed with different scanner models (mostly Somatom Definition Flash or Force, Siemens Healthcare, Forchheim, Germany) and center-specific scanning protocols. In most of the cases, a retrospective ECG-gated data acquisition was performed by means of bolus tracking. The amount of iodinated contrast agent varied between 50 and 100 mL, depending on the center and the timing of scanning (pre- or post-TAVI). For the most part, raw data were reconstructed in 50ms- or 5%-steps throughout the cardiac cycle. Four of the participating centers performed routine post-TAVI CTA in all eligible patients with a median interval of 8.5 [IQR 4,25;12] days after the procedure, usually pre-discharged between day 2 and 12 after TAVI. This was performed according the guidelines after thoracic aortic stent implantation[10]. The intention was to identify possible complications, e.g. aortic injuries, thrombosis of the valves, underexpansion of the prosthesis.

Statistical analysis

All statistical analyses were performed using SPSS software (SPSS version 23.0, SPSS, Chicago, Illinois). Continuous variables are reported as mean and standard deviation (SD). Categorical variables are reported as frequencies and percentages.

Results

A total of 21 patients with a contained rupture post-TAVI were identified between July 2008 and October 2017. In the four centers performing routine post-TAVI CTA, CRs were delineated in 17 out of the 1602 (1.1%) patients (Figure 2). In one of these cases a hemodynamically relevant pericardial effusion had to be drained during the TAVI procedure, but the patient was

asymptomatic at the time of the CR diagnosis on post-TAVI CTA. The periprocedural echocardiographic monitoring of the remaining 16 patients was unremarkable.

In two of the other four patients, periprocedural transesophageal or transthoracic echocardiography revealed findings suggestive of an aortic intramural hematoma and a pericardial effusion. Due to these findings post-TAVI CTA was conducted which demonstrated a CR with questionable causal association to the initial findings. The CR of the remaining two patients was delineated in peri- and postprocedural TEE.

For the overall cohort the mean interval (SD) from TAVI-procedure to diagnosis was 16±15 days. The baseline echocardiographic and computed tomography characteristics are summarized in Table 1. The mean age of the patients-cohort with CR was 81.9±4.1 years, 18 females (86%) with a mean logistic EuroSCORE of 12.9±5.1 and STS-score of 4.4±1.4%. The majority of the cases occurred after choosing a transfemoral access route (n=17, 81%) or implantation of balloon-expandable valve types in 17 (81%) patients. A postdilatation was performed in each of the four CRs occurring after the implantation of self-expandable THVs. The mean THV oversizing (based on the annular area) was 23.0±11.4 %.

In pre-TAVI CTA the highest amount of calcification of the device landing zone was found next to the non-coronary cusp (Table 1), whereas the contained ruptures were located in 13 (62%) of the cases adjacent to the left coronary cusp (Table 2). The mean size of the lesions was 15±7x9±3x9±2 mm with a maximum size of 24x17x14 mm resulting in a cranial shift of the left main stem (Figure 3, Table 2). Only the case with the largest CR was detectable by transthoracic echocardiography. During the index hospital stay none of the patients were symptomatic or received any specific treatment for CR. Table 2 summarizes the periprocedural characteristics as well as in-hospital events.

Antithrombotic treatment

In 19 of the 21 cases the antithrombotic was not altered after diagnosis of CR. Thus, standard dual antiplatelet therapy (DAPT) was administered in 12 patients and 7 patients with atrial fibrillation received antiplatelet monotherapy plus anticoagulation for the first six to twelve months depending on concomitant percutaneous coronary intervention. One patient received aspirin-monotherapy after CR diagnosis instead of DAPT and one patient with atrial fibrillation warfarin solely without aspirin.

Follow-up

The mean follow-up time of the overall cohort was 2.3±1.7 years (cumulative 48.6 patient years) with a maximum observation length of 5.1 years (1843 days). During the follow-up period none of the 21 patients exhibited symptoms, underwent interventional treatment or died related to the CR. None of the patients died through a sudden cardiac death. Nine patients (43%) died from non-cardiac causes (e.g. acute kidney or respiratory failure, infection). At least one follow-up CTA was performed in 11 (52%) patients with a mean time to last follow-up CTA of 240±176 days. These follow-up CTAs revealed stable CR findings in seven (64%), regression in one (9%), and a complete remission in three patients (27%) (Figure 4).

Discussion

Our study is the first to report the long-term outcomes in patients with post-TAVI CR in a large, international multicenter registry. Our results suggest a favourable course of this complication over a mean follow-up period of 2.3±1.7 years.

Short-term follow-up studies, case reports with follow-up of up to 6 months and a recently published cases series demonstrated favourable outcomes of CR[2,3,6,7]. The current registry adds to these studies by providing CR longer-term follow-up in a large series of consecutive patients

having CTA performed following TAVI with various valve designs. Thus, we were able to expand the information on the benign nature of contained rupture substantially compared with these previous observational studies.

Two previous case reports describe a complicated course of contained ruptures. Erez et al. report of a patient with contained rupture resulting in compression of the left main coronary artery, treated by percutaneous intervention[4]. Himbert et al. published a case of CR with sudden death of unknown cause within the first month post TAVI[11].

In contrast to these reports all our patients were asymptomatic during in-hospital stay and no specific treatment was necessary. All patients remained asymptomatic during the follow-up period. In 11 of our patients with at least one additional follow-up CTA, CR sizes were stable findings, demonstrate partial or complete regression. This is in accordance with our previously published study, where we observed stable CTA findings in 60 % of the patients and complete regression in 40 % after a comparable follow-up period[8].

CR of the aortic annulus after TAVI with balloon-expandable THVs have been described previously with an estimated incidence of approximately 5% and commonly present as an incidental finding on post-TAVI CTA[3]. The lower incidence in our study compared with this from Blanke et al. (1.1% vs. 5.0%) may be explained by differences in crucial determinants of outcome between studies, e.g. cohort size (1602 vs. 65 patients), a changed THV design with newer valve generations and more knowledge about risk factors for CR over time[3]. The majority of cases (62%) in the ENCORE-registry occurred after the implantation of an earlier generation of balloon-expandable THVs (Sapien XT). The sample size and the registry design of our study did not allow reliable analyses of predictors of contained ruptures. Nevertheless it is tempting to speculate that the risk for CR diminishes by using new generation THVs, more optimal THV sizing and growing experiences about the TAVI-procedure.

In accordance with formerly identified and described predictors for aortic root injury, the mean

prosthesis oversizing was over ≥ 20% in our cohort and we identified pronounced calcifications in the left ventricular outflow tract, in particular adjacent the non-coronary cups[2,3]. Furthermore, all patients with a CR after implantation of a self-expandable THV underwent peri-interventional postdilatation. Even if the registry was not designed to analyze risk factors, one might assume that avoiding postdilatation may prevent CRs especially in patients with self-expandable prostheses.

Consistent with previous reports, most (61.9%) of these contained ruptures were located adjacent to the left coronary cusp[3,12]. Blanke et al. defined the tissue in this region of the aortic root as a "locus minoris resistentiae"[3]. Furthermore, pronounced calcification in the non-coronary valve region could force the frame to overexpand on the left-coronary side.

A relatively high proportion of peri-interventional pericardial effusions (19%) were noted in our cohort. One might assume that the annulus rupture was initially uncontained with a small temporary outflow into the pericardial space. Another possible reason for the pericardial effusion could be an injury of the myocardium through a peri-interventional insertion of a temporary pacemaker electrode. Since all ruptures were contained without communication to the pericardium at the time of diagnosis, the exact mechanism remains unclear. However, none of pericardial effusions resulted in a need for surgical intervention.

The results of our registry show a favourable course of a CR even with continuation of the standard antithrombotic treatment. Therefore, DAPT or antiplatelet monotherapy plus anticoagulation (in patients with an appropriate indication) may be considered in patients with a CR.

Limitations

Only 4 of the 6 TAVI-centers in our registry performed routine post-TAVI CTA. Due to the clinical characteristics of our patient cohort the post-TAVI CTA rate was limited with

approximately 60 % of the TAVI-patients. Therefore, a number of contained ruptures and their corresponding follow-up may have been missed. Furthermore, we cannot exclude deaths due to non-diagnosed uncontained CR immediately after procedure before performing the post-TAVI CTA. Due to the lack of follow-up CTAs in 10 patients (48%) we cannot entirely rule out progression of the CR in some cases. However, none of the CR-patients developed symptoms during follow-up and there was no progression in patients with follow-up CTA. Due to missing data of patients without CR, a calculation of incidences for self- and balloon-expandable or older and newer generation THVs was not possible. Furthermore, we cannot exclude an increased risk of overt rupture or other complications, particularly during longer term follow-up. Despite the limitations, in particular, given the low incidence of contained ruptures post-TAVI (1.1%), our follow-up data from 21 CR-patients can clarify the question of the best therapy for this TAVI complication.

Conclusion

The results of our large international registry suggest a favourable course of initially asymptomatic contained ruptures of the aortic annulus after TAVI supporting a watch-and-wait approach in these patients. Thus, no specific treatment seems to be necessary.

Impact on daily practice

In view of the fact, that further increasing numbers of worldwide TAVI-procedures are expected, adequate knowledge in dealing with complications is necessary. Based on the results of our ENCORE-registry, a watch-and-wait strategy without specific treatment should be preferred in patients with an asymptomatic contained rupture of the aortic annulus after

TAVI. Scientific evidence of a conservative approach is particularly important in TAVI complications, because the initial decision for an interventional treatment of aortic valve stenosis should actually avoid surgery for these patients.

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Figure legends

Figure 1 – Illustration of the definition of a contained rupture in post-TAVI CTA

Contrast-enhanced retrospectively ECG-gated CTA axial reconstructions of the device landing zone showing a contained rupture as a peri-annular pseudo-aneurysm formation (brace) with the integrity of all vascular wall layers and a connection to the intra-aortic lumen (<->double arrow).

Figure 2 - Flowchart of patients who underwent TAVI within the centers of the registry with routine post-TAVI CTA

1) Exclusion criteria were: acute renal failure or presence of severely impaired renal function (creatinine-clearance < 30 ml/min), post-TAVI severely reduced general state of health. 2) Incidence of contained ruptures of the aortic annulus within the patients who underwent post-TAVI CTA.

Figure 3 – Pronounced finding of a contained rupture leading to a left main stem shift

Contrast-enhanced retrospectively ECG-gated CTA axial and sagittal oblique reconstructions showing a contained rupture of the aortic annulus **(→arrow in A, B)** 9 days after transcatheter aortic valve replacement with the maximum detected size of 24x17x14 mm in a 84-year old female. The contained rupture led to a cranial shift of the left main stem **(---> dashed arrow in B)**.

Figure 4 – Complete remission of a contained rupture during follow-up

Contrast-enhanced retrospectively ECG-gated CTA axial and sagittal oblique reconstructions showing a contained rupture **(arrow in A, B)** of the aortic annulus in a 77-year old female 15 days after transcatheter aortic valve replacement **(A, B,)**, the follow-up CTA after 8 months showing a complete remission of the contained rupture **(C, D)**. Differences between the CTA images (A and B vs. C and D) regarding the adjacent structures are caused by a different time point of image reconstruction throughout the cardiac cycle (for the figures we chose the time point with the fewest artefacts).

Table 1. Baseline characteristics, echocardiographic and computed tomography characteristics pre-TAVI of the patients with later identified contained annulus ruptures.

Characteristics	Contained rupture patients
Age, years	81.9±4.1
Female sex, n (%)	18 (85.7)
NYHA classification of heart failure	
II	3 (14.3)
III	18 (85.7)
STS score, %	4.4±1.4
log EuroSCORE, %	12.9±5.1
Previous PCI, n (%)	3 (14.3)
Atrial fibrillation, n (%)	8 (38.1)
Echocardiographic findings	
Aortic valve area, cm²	0.7±0.1
Mean aortic valve gradient, mmHg	55.8±18.5
Peak of velocity aortic valve, m/s	4.7±0.9
Ejection fraction, %	56.3±5.1
LVEDD, mm	44.4±5.6
Sinus of valsalva, mm	30.5±2.0
Tricuspid aortic valve, n (%)	18 (85.7)
Computed tomography findings	
Aortic annulus area, mm²	420.5±40.8
Aortic annulus diameter, mm	23.1±1.1
Sinus of Valsalva diameter, mm	30.1±2.0
Ascending aorta diameter, mm	30.3±6.4
Degree of calcification of the device landing zone	
Left coronary cusp, scale 1-4*	2.6±1.1
Right coronary cusp, scale 1-4*	2.0±0.9

	Non-coronary cusp, scale 1-4*	3.2±1.0

Values are mean ± standard deviation or n (%).*4-point scale for calcification: 1 mild; 2 moderate, 3 severe calcifications; 4 massive calcifications. log EuroSCORE: logistic EuroScore. LVEDD: left ventricular end diastolic diameter. NYHA = New York Health Association Functional Classification. PCI: percutaneous coronary intervention. STS score: Society of Thoracic Surgeons predicted Risk of Mortality.

Table 2. Procedural characteristics, periprocedural and in-hospital complications of the patients with contained annulus rupture post-TAVI.

Degree of THV oversizing (based on annular area), %	23.0±11.4
TAVI access route	
Transfemoral, n (%)	17 (81.0)
Transapical, n (%)	3 (14.3)
Transsubclavian, n (%)	1 (4,8)
Implanted THVs	
Balloon-expandable prosthesis	
Sapien XT	13 (61.9)
Sapien S3	4 (19.0)
Self-expandable prosthesis	
Evolut R	3 (14.3)
Acurate Neo	1 (4.8)
Postdilatation, n (%)	7 (33.3)
Mean size of the contained rupture, mm	15±7x9±3x9±2
Location/region of the contained rupture	
Left coronary cusp, n (%)	13 (61.9)
Right coronary cusp, n (%)	4 (19.0)
Non-coronary cusp, n (%)	4 (19.0)
Periprocedural and in-hospital complications	
Major vascular complication, n (%)	1 (4.8)
Cerebrovascular event*, n (%)	2 (9.5)
New permanent pacemaker+, n (%)	6 (28.6)
Acute kidney injury, n (%)	1 (4.8)
Pericardial effusion, n (%)	4 (19.0)
Hemothorax, n (%)	1 (4.8)

Pneumothorax (transapical approach), n (%)	1 (4.8)
Aortic intramural haematoma, n (%)	1 (4.8)

Values are mean ± standard deviation or n (%). *During the first 30 days post-TAVI. THV: Transcatheter heart valve.